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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,687	11/12/2003	David E. Wolf	04037-011002	6999
26191	7590	06/29/2006	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			YOON, TAE H	
			ART UNIT	PAPER NUMBER
			1714	
DATE MAILED: 06/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/706,687

Applicant(s)

WOLF, DAVID E.

Examiner

Tae H. Yoon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Examples 1 and 2 show a method of coating beads (core) with PLL solution. Said PLL solution would mean that said PLL is dissolved in a stock solution, and such solution would not yield a coating having monodispersed PLL particles, but random PLL particles.

Claims 1-14, 16 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a coated gel, does not reasonably provide enablement for a coated aqueous solution. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The application failed to teach how to obtain a coated aqueous solution. Note that the examples teach utilization of PLL solution, and thus the examiner does not see how to coat an aqueous solution with PLL solution, for example.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "said coating comprising a monodisperse polymer" in claim 1 is confusing since it is unclear whether said monodisperse polymer is directed to the coating on a core or an article itself (article is monodispersed).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 and 19-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-26 and 31-82 of U.S.

Patent No. 6,126,936. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the composite microreactor of said patent encompasses the instant article having a monodisperse polymer as evidenced by example 2 (600 μm spheres are taught) of said patent. Polylysine having a coating of different molecular weights meets the claim 20 since the difference is not defined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 6, 8-11, 13-16 and 19-21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goosen et al (US 4,806,355).

Goosen et al teach an article comprising a core and a selectively permeable coating enclosing the core in abstract and example 1. Said example 1 teaches

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polylysine having a molecular weight 25,000 which would be a monodispersed polymer inherently since each polymer chain has the same length. Polylysine and other polyamino acids have molecular weights of 11,000 to 100,000 (col. 3, line 66 to col. 4, line 11), and a polymer having a molecular weight of 11,000 inherently contains less than 300 monomeric units since the MW of L-lysine is 146. Goosen et al further teach heteropolymers (example 3), an alginate hydrogel core (col. 5, line 26) and a second and different monodisperse polymer coating (col. 6, lines 31-46 and examples 8 and 9). Goosen et al teach the same method used in the instant invention, the use of polylysine solution to coat hydrogels, and thus it would meet the invention regardless of the issue raised in above 112, 2nd PP rejection.

Thus, the instant invention lacks novelty.

Claims 1-16 and 19-21 are rejected under 35 U.S.C. 103(a) as obvious over Goosen et al (US 4,806,355).

The instant invention further recites polymeric molecular weights of 1,000 to 4,000, monomeric units of 10 to 40 and 20 to 30 and a second coating of a monodisperse polymer over Goosen et al. However, Goosen et al teach that the molecular weight of polyamino polymer varies depending on the porosity required at the top of col. 4.

Thus, it would have been obvious to one skilled in the art at the time of invention to utilize polyamino polymer having a molecular weight of 1,000 to 4,000 or monomeric

units of 10 to 40 and 20 to 30 in Goosen et al since Goosen et al teach such modification (use of other molecular weight).

Claims 1-3, 5, 6, 8-11, 13-17 and 19-21 are rejected under 35 U.S.C. 103(a) as obvious over Goosen et al (US 4,806,355) and Kliment et al (US 3,551,556).

Claim 17 further recites vinyl polymers as a gel over Goosen et al. However, the use of the instant polymers as polymeric carriers for biological applications is well known as taught by Kliment et al, col. 1, line 54 to col. 2, line 16.

Thus, it would have been obvious to one skilled in the art at the time of invention to utilize vinyl polymers such as polyacrylamide of Kliment et al as a carrier polymer in Goosen et al since Goosen et al teach employing a polymeric carrier and since said polyacrylamide is well known carrier for biological applications absent showing otherwise.

Claims 1,2, 5, 8-11, 13-16, 19 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weber et al (US 5,227,298).

Weber et al teach a double walled bead containing a gelled core (viable tissues or cells, or alginate) at col. 6, lines 45-68. The use of poly-L-lysine having a molecular weight of 18kd is taught at col. 7, line 33 and col. 8, line 34, and it would be a monodispersed polymer inherently since it has one molecular weight. Said polymer having a molecular weight of 18,000 inherently contains less than 300 monomeric units.

The use of a second coating with said poly-L-lysine is taught at col. 7, lines 54-63.

Weber et al teach the same method used in the instant invention, the use of poly-L-lysine solution to coat hydrogels, and thus it would meet the invention regardless of the issue raised in above 112, 2nd PP rejection.

Thus, the instant invention lacks novelty.

Claims 1, 2, 5, 8-11, 13-16 and 19-21 are rejected under 35 U.S.C. 103(a) as obvious over Weber et al (US 5,227,298).

The instant invention further recites a second monodisperse polymer different from the first monodisperse polymer Weber et al.

However, it would have been obvious to one skilled in the art at the time of invention to utilize other polymer such as polyamino acid or polyethyleneimine having the same molecular weight as a second coating since Weber et al teach other polymer coating at col. 7, lines 29-30 absent showing otherwise.

Claims 1, 2, 5, 8-11, 13-17 and 19-21 are rejected under 35 U.S.C. 103(a) as obvious over Weber et al (US 5,227,298) and Kliment et al (US 3,551,556).

Claim 17 further recites vinyl polymers as a gel over Weber et al. However, the use of the instant polymers as polymeric carriers for biological applications is well known as taught by Kliment et al, col. 1, line 54 to col. 2, line 16.

Thus, it would have been obvious to one skilled in the art at the time of invention to utilize vinyl polymers such as polyacrylamide of Kliment et al as a carrier polymer in

Weber et al since Weber et al teach employing a polymeric carrier and since said polyacrylamide is well known carrier for biological applications absent showing otherwise.

Claims 1-16 and 19-21 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lanza et al (US 6,126,936).

Lanza et al teach the instant invention in example 2 wherein 600 μm spheres are taught. Polylysine having a coating of different molecular weights meets the claim 20 since the difference is not defined. Polylysine having a molecular weight of 1,000 to 4,000 is taught at col. 22, lines 1-5, and said polylysine inherently possesses the instant monomeric units.

Thus, the instant invention lacks novelty.

Claims 1-17 and 19-21 are rejected under 35 U.S.C. 103(a) as obvious over Lanza et al (US 6,126,936) and Kliment et al (US 3,551,556).

Claim 17 further recites vinyl polymers as a gel over Lanza et al. However, the use of the instant polymers as polymeric carriers for biological applications is well known as taught by Kliment et al, col. 1, line 54 to col. 2, line 16.

Thus, it would have been obvious to one skilled in the art at the time of invention to utilize vinyl polymers such as polyacrylamide of Kliment et al as a carrier polymer in Lanza et al since Lanza et al teach employing a polymeric carrier and since said polyacrylamide is well known carrier for biological applications and since Lanza et al


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teach employing other synthetic polymers at col. 28, lines 40-52 absent showing otherwise.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tae H. Yoon whose telephone number is (571) 272-1128. The examiner can normally be reached on Mon-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Tae H Yoon
Primary Examiner
Art Unit 1714

THY/June 24, 2006